Remarks

Claim 1 has been amended to add the phrase "up to 30 days and". Basis for this amendment can be found in the specification on page 24, line 1. Claim 6 has been amended to depend upon claim 1 rather than claim 2. Claims 4, 5, 17, and 24 have been canceled. New claims 35, 36, and 37 have been added. Basis for new claims 35 and 36 can be found in the specification, at the very least, on page 22, lines 3 to 8. Basis for new claim 37 can be found, at the very least, on page 23, lines 31-34 and page 24, lines 1-2. It is respectfully submitted that no new matter has been introduced into the specification.

Applicants also wish to bring to the attention of the Office that the word "embonate" is equivalent to the word "pamoate". That is, embonic acid and pamoic acid are the same chemical entity. In this regard, several of the references which have been brought to the attention of the Office in the attached Information Disclosure Statement use the "embonate" nomenclature rather than the "pamoate" nomenclature.

Claim Rejection under 35 U.S.C § 112, First Paragraph

The Office rejected claims 1, 4-7, 10-17, and 21-24 under 35 U.S.C § 112, first paragraph, as failing to comply with the written description requirement. In response, Applicants submit that claim 1 has been amended to add the phrase "up to 30 days and" after the phrase "wherein said formulation has a prolonged sustained release of greater than 7 days and" pursuant to the Office's recommendation.

The Office further submitted that claim 1 requires "oleaginous carrier" and "cholesterol microsphere carrier", while claim 4 limits the carrier to non-ionic copolymers of propylene oxide and ethylene oxide, cellulose gums, polysaccharide gums, vegetable oils, refined fractionated oils, sucrose diacetate hexaisobutyrate, lecithin and polyvinyl pyrrolidine. Hence, the Office asserted that there is no description stating which carrier is "oleaginous" and which carrier is "cholesterol microsphere carrier." In view of this rejection, Applicants submit that claim 4 has been cancelled obviating the present rejection.

As a result of the above amendment to claim 1 and cancellation of claim 4, Applicants submit that rejection of claims 1, 4-7, 10-17, and 21-24 under 35 U.S.C § 112, first paragraph, has been obviated.

Claim Rejection under 35 U.S.C § 112, Second Paragraph

The Office rejected claims 4-7, 10-17, and 21-24 under 35 U.S.C § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. The Office submitted that it is not clear how the carriers in claims 4 and 5 limit "oleaginous carrier" or "cholesterol microsphere carrier". In addition, the Office submitted that for claim 17, propylene oxide-ethylene oxide copolymer (PLURONIC), cellulosic gum and polysaccharide gum do not appear to be oleaginous or oils. Furthermore, the Office noted that claim 6 depends upon cancelled claim 2. The Office further submitted that the particle size recited in claim 24 is outside the particle size recited in claim 23. Finally, the Office asserted that a "burst release of less than 15% of the active ingredient" is unclear, and that explanation/correction is respectfully requested.

In view of the above, Applicants submit that claims 4, 5, 17, and 24 have been cancelled, and claim 6 has been amended to properly depend upon claim 1 rather than cancelled claim 2. Regarding the phrase "burst release of less than 15% of the active ingredient", Applicants respectfully submit that the word "burst" is defined on page 24, lines 2-4 of the specification wherein it states, "The term "burst" is understood by those skilled in the art to mean the immediate release of active ingredient." Hence, Applicants respectfully submit that one of ordinary skill in the art would understand that a burst release of less than 15% of the active ingredient as used in the claims means that there is less than 15% of the active ingredient released immediately upon administration to the patient by intramuscular injection. In view of the above amendments and explanation, Applicants respectfully submit that the rejection of claims 4-7, 10-17, and 21-24 under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention has been obviated.

Claim Rejection under Double Patenting

The Office rejected claims 1, 4-7, 10-17, 21-24, and 34 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, and 7 of the U.S. Patent No. 6,169,084 in view of Baxter et al. (US H0,000,672 H).

While Applicants do not necessarily agree with the Office's assessment of the claims under the obviousness-type double patenting rejection, Applicants provide, only in order to expedite prosecution, a terminal disclaimer pursuant to 37 C.F.R. § 1.321. Applicants further submit that the filing of this terminal disclaimer is not an admission or an acquiescence by, nor shall act as an estoppel upon the Applicants on the merits of the rejection.

In view of the presently submitted terminal disclaimer, Applicants respectfully submit that rejection of claims 1, 4-7, 10-17, 21-24, and 34 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, and 7 of the U.S.

Patent No. 6,169,084 in view of Baxter et al. has been obviated.

In view of the above amendments, remarks, and terminal disclaimer, Applicants submit that claims 1, 3, 6, 7, 10-16, 21-23, and 34-37 are in condition for allowance. Reconsideration and withdrawal of the rejection is respectfully requested, and allowance of claims 1, 3, 6, 7, 10-16, 21-23, and 34-37 is kindly solicited.

Respectfully submitted,

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